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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/364,908

Applicant(s)

MAINGAULT ET AL

Examiner

Jean C. Witz

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
4. ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Other \_\_\_\_\_

## DETAILED ACTION

### *Continued Prosecution Application*

1. The request filed on July 5, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/364908 is acceptable and a CPA has been established. An action on the CPA follows.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 17-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francesco et al. combined with WO 9637519.

Francesco et al. teaches hydrogel compositions comprising esterified polysaccharide macromolecules (alginic acid or hyaluronic acid) with aliphatic chains

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which can exist either as a gel or can be solubilized. The aliphatic chains can be attached either via tetrabutyl ammonium salts of the carboxylic acid residues of the macromolecules or via esterification of the carboxylic acid residues with an aliphatic amine. The remaining carboxylic acid residues are converted to sodium salts. See, for example, Example 2 and Column 13, lines 15-50. It is inherent in the disclosure of the reference that these molecules that interactions occur between the aliphatic chains of various macromolecules. The aliphatic chains are disclosed as preferably having 6 carbons. Finally, medicaments are combined with the hydrogels as a drug delivery system. Specifically, the compositions are described as being used for ophthalmological applications where excellent adhesion to the corneal epithelium is desired. At col. 16, lines 16-19, the reference states that "In the field of ophthalmology, the indications can be in particular for example, miotic, anti-inflammatory, wound healing and antimicrobial effects". Further down in col. 16, at lines 57-64, the reference states that "According to one particular aspect of the invention it is possible to prepare the medicaments of this type starting with the previously isolated and possibly purified salts and, in their solid anhydrous state, as an amorphous powder, which on contact with the tissue to be treated constitute a concentrated aqueous solution of a gelatinous character with viscous consistency and elastic properties."

While the reference does not explicitly state that the product is to be applied as a solution and then caused to change into a gel state, it is clear from the disclosure of the patent that Francesco et al. were aware of the changeability of the state of the alginate products and were aware of the benefits of the gel state as applied to a treated surface.

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Further, Francesco et al. identified wound-healing as an indication to be treated with the compositions of the reference. The claims make no mention as to the site of the wound.

WO 9637519 teaches hydrogel compositions comprising esterified polysaccharide macromolecules (alginic acid or hyaluronic acid) with aliphatic chains which can exist either as a gel or can be solubilized. The aliphatic chains are attached either via tetrabutyl ammonium salts of the carboxylic acid residues of the macromolecules. The remaining carboxylic acid residues are converted to sodium salts. It is inherent in the disclosure of this reference that these molecules that interactions occur between the aliphatic chains of various macromolecules. The aliphatic chains are disclosed as preferably having 6 carbons. Finally, medicaments or cells are combined with the hydrogels as a drug delivery system or as a support for the transplantation of cells. Specifically at page 5 of the reference, the reference states that it is known that the formation of viscoelastic gels from the solution of the polymers can be obtained by the exposure to a catalyst and ultraviolet radiation. As a result, the reference states that the polymers have use in the area of medicine and surgery and at page 6 specifically state that the polymers adhere to tissue surfaces. At page 7 of the reference the hydrogel material is described as being "advantageously used as agents to enable cell-cell interactions and cell-polymer interactions, as they can act as material for cell recruitment, as fillers in replacements for example in breast replacements, as fillers for dental cavities and in cosmetic surgery, as fillers, in place of collagen, for small areas or cavities in soft tissue." At page 8, the reference states that "In particular when

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this medicament is administered by topical or oral route, it is preferably in the form of a gel.

While the reference does not explicitly state that the product is to be applied as a solution and then caused to change into a gel state, it is even clearer from the disclosure of this reference that one of ordinary skill in the art was aware not only of the changeability of the state of the alginate products and of the benefits of the gel state as applied to a treated surface, but also aware of the use of the viscoelastic hydrogel as both a filler of tissue cavities and as a carrier for both medicaments and cells for the treatment of tissue cavities. Further, the reference identifies medicaments that are used in woundhealing as included in the hydrogels.

It is clear that partial esterification of alginic acid or hyaluronic acid with aliphatic chains is conventional and results in compositions that can reversibly change from aqueous solutions to viscoelastic hydrogels. Both references engage in the same processes of producing the compositions as disclosed by Applicants and use aliphatic chains having myriad of different lengths and chemical character. Chains of about 6 carbons are conventionally used. These modified polysaccharide molecules can exist as hydrogels or in solution, and are conventionally used as delivery vehicles for medicaments and for support for transplantation of cells. It is clear that selecting the specific aliphatic chain and the degree of esterification is well within the skill of the practitioner such that optimization of specific gel-sol parameters as desired would have been obvious to one of ordinary skill in the art at the time the invention was made. Finally, the disclosures of both references clearly suggest that the adhesion and

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viscoelastic qualities of the hydrogels make them excellent fillers for tissue cavities and defects including wounds. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to apply the composition as a solution to encourage complete filling of the cavity and then covert the composition to a hydrogel to ensure adhesion to the tissue surface and retention of the composition in the wound cavity.

### ***Response to Arguments***

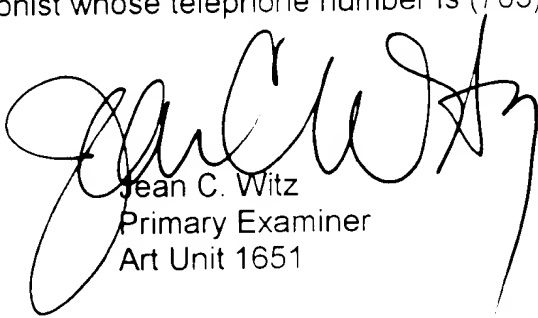
5. Applicants' arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Applicants merely assert that the prior art does not apply but fails to address the references' recitations with regard to treatment of wounds and tissue cavities.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz  
Primary Examiner  
Art Unit 1651

September 9, 2001